

Docket No.: 284112US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :  
ATSUSHI YAMAGISHI, et al. : EXAMINER: SUTTON, D.C.  
SERIAL NO.: 10/564,368 :  
FILED: JANUARY 12, 2006 : ART UNIT: 1612  
FOR: ORAL ACTIVITY COMPOSITION

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

Sir:

Now comes Mr. Atsushi Yamagishi who deposes and states that:

1. I am a graduate of the Graduate School of Nagaoka University of Technology, Materials Science and Technology, and received my Master's degree in the field of Materials Science and Technology, in the year 1988.

2. I have been employed by Kao Corporation, for 20 years involved in research and development of hair care products from 1988 to 1999 and then involved in research and development of oral products from 1999 to present.

3. I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.

4. The following experiments were carried out by me or under my direct supervision and control.

5. The following experimental procedure was followed:

Two-part compositions (one claimed product and three comparative examples) were prepared as shown in Table 1 below. Part A and Part B of each composition were diluted with artificial saliva as shown in Table 2A and 2B to 3 fold and used in the following procedure.

A HAP pellet was immersed alternately in Part A solution and Part B solution (for 10 seconds for each solution). This treatment was repeated 3 cycles. For Comparative example B1, a HAP pellet was also immersed once in a mixture of Part A and Part B for 3 minutes.

Table 1

		(wt %)			
		Comp. Ex. B1  (US5,858,333 Example 5)	Comp. Ex. B2	Example (Claimed product)	Comp. Ex. B3
A	Calcium nitrate	3.8	3.8	-	-
	Calcium glycerophosphate	-	-	3.42	3.42
	Glycerine	25	25	25	25
	MFP <sup>*)</sup>	-	1.89	1.89	1.89
	Purified water	74	balance	balance	balance
		pH 8.1			
B	Potassium phosphate (anhydrous)	4	4	4	4
	Sodium fluoride	0.55	0.55	0.55	-
	Glycerine	25	25	25	25
	Purified water	balance	balance	balance	balance
	Acetate	q.s.	q.s.	q.s.	q.s.
		pH about 4			
pH in a mixture		5.5	5.5	5.5	5.5
fluorine uptake 1 ( $\mu\text{g}/\text{cm}^2$ ) <sup>*)</sup>		0.75	0.82	2.00	0.05
fluorine uptake 2 ( $\mu\text{g}/\text{cm}^2$ ) <sup>*)</sup>		1.2	-	-	-

\*1) The molar amount of MFP was comparative to that of 0.55wt% of sodium fluoride

\*2) 3 times immersion

\*3) 3 minutes immersion just after preparing the mixture of Part A and Part B

Table 2A: Components of artificial saliva

	mM	g/L
CaCl <sub>2</sub>	1.5	0.1665
KH <sub>2</sub> PO <sub>4</sub>	5	0.6805
NaCl	5	0.2925
KCl	20	1.49
NaHCO <sub>3</sub>	3	0.252
		pH 7.0

Table 2B: Ionic concentration in artificial saliva

Ion species	Total (mM)
Ca	1.5
PO <sub>4</sub>	5
Na	8
K	25
Cl	29.5
HCO <sub>3</sub>	3

6. The following results were obtained

As shown in Table 1 above, the amount of fluorine uptake derived from the claimed product was nearly three times larger ( $2.00 \mu\text{g}/\text{cm}^2$  vs.  $0.75 \mu\text{g}/\text{cm}^2$ ) than that derived from Comparative Example B1 (Example 5 composition of US 5,858,333 ("Winston")). Comparing with the Comparative Example B2, which is the Example 5 composition of Winston further containing MFP in Part A, the claimed product resulted in more than two-fold fluorine uptake ( $2.00 \mu\text{g}/\text{cm}^2$  vs.  $0.82 \mu\text{g}/\text{cm}^2$ ). In Comparative Example B3, in which MFP was contained in Part A as the only fluorine supplier, fluorine uptake was poor (0.05).

7. The foregoing comparative experiment compared the claimed product to Example 5 of Winston, which, of the Examples, provides the highest increase in hardness (see Table VII) and believed the best comparative example to the claimed product. Example 3 of Winston could not be replicated for this comparison because the Example 3 composition was difficult to mix and prepare well due to the low water content in Part B.

8. Winston disclose that the cationic part (i.e., Part A) may contain MFP (monofluorophosphate) with calcium salt, but it is less desirable due to the potential loss of fluoride (see, column 9, lines 17-21). As a result, Winston does not provide any Examples in which MFP is used. Thus, based on the disclosure of Winston, the artisan would have

expected that the presence of MFP in the cationic part (i.e., Part A) would result in the loss of fluoride and would be dissuaded from using MFP in this part. Indeed, as illustrated in Comparative Example B2 above, adding MFP to part A of Example 5 of Winston resulted in poor fluorine uptake.

In contrast to the expectation presented by the disclosure of Winston, the claimed product, which includes MFP with calcium salt (i.e., in Part A), leads to excellent fluoride uptake rather than resulting in loss of fluoride (see, Table 1 above). Such excellent fluoride uptake (i.e., two-fold over Winston's composition with MFP in Part A and nearly three-fold of Winston's exemplified composition) provided by the claimed invention is in no way expected from the disclosure of Winston.

This result is also unexpected even when considering the disclosures of US 4,048,300 (Tomlinson), US 4,083,955 (Grabenstetter), and/or US 6,287,120 (Wiesel).

9. I declare further that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

10. Further Declarant saith not

Atsushi Yamagishi  
Name: Atsushi Yamagishi

February 20, 2009  
Date